DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–384L, 91N–0384, and 84N–0153]

RIN 0905–AD08

Food Labeling: Label Statements on Foods for Special Dietary Use; ''Useful Only in Not Promoting Tooth Decay'' Disclaimer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of request for a hearing; confirmation of effective date; denial of requests for a stay of effective date and for reconsideration.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests for a hearing on the objections to its final rule that amended the regulations on foods for special dietary use to conform them to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). After reviewing the objections to the amendment and the request for a hearing, the agency has concluded that the objections do not raise an issue of material fact that justifies granting a hearing or revoking the agency's action. Nor have they convinced the agency that it is appropriate for it to revoke its action. The agency also received requests for a stay of the effective date of the final rule and for reconsideration of the decision concerning the use of the ''Useful Only in Not Promoting Tooth Decay'' disclaimer for ''sugar-free'' foods. FDA is denying these requests. FDA is confirming the effective date of the final rule.

EFFECTIVE DATE: May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Introduction

Prior to 1993, FDA regulated ''no-'' and ''low-calorie'' foods as foods for special dietary use under part 105 (21 CFR part 105). FDA had promulgated § 105.66 to provide for label statements on products for reducing or maintaining caloric intake or body weight. Terms such as ''low calorie,'' ''reduced calorie,'' and ''sugar free,'' which could be used to highlight foods useful in the maintenance or reduction of body weight, were included in this section.

Over time, however, more and more people have become concerned with healthier eating and have begun to follow the suggestion in Dietary Guidelines for Americans to maintain a healthy weight. Consequently, terms such as ''low'' or ''reduced calories'' and ''sugarless'' have come to be used on foods intended for consumption by the general population. As such, these terms have lost their special significance in the labeling of foods intended solely for special dietary uses. Accordingly, FDA came to see that these terms should be defined under the 1990 amendments as nutrient content claims.

In the **Federal Register** of November 27, 1991 (56 FR 60421), the agency published a document entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms'' (hereinafter referred to as the nutrient content claims proposal). In that document, FDA proposed to define terms that describe the caloric level in a food and related sugar claims, terms which had been regulated as special dietary use claims in §§ 105.66 and 101.60 (21 CFR 101.60), as nutrient content claims.

In particular, FDA proposed to define the terms ''low calorie,'' ''reduced calorie,'' ''sugar free,'' and ''no added sugar'' in § 101.60. Because the definitions of these terms in § 105.66 would be redundant, and because these terms would no longer be necessary as special dietary use claims, FDA proposed in the nutrient content claims proposal to revise § 105.66 (c), (d), and (f) to reference the appropriate paragraphs in § 101.60. At the same time, FDA proposed in § 101.60(o)(8) to permit sugarless chewing gums to bear sugar free claims provided that the label also bear, when the food is not low or reduced calorie, a statement such as ''Not a reduced calorie food,'' ''Not a low calorie food,'' ''Not for weight control,'' or ''Useful Only in Not Promoting Tooth Decay.'' The agency also noted that it planned to reevaluate the determination of usefulness in not promoting tooth decay of gums sweetened with sugar alcohols (56 FR 60421 at 60437).

FDA tentatively concluded, however, that there was a significant portion of § 105.66 that remained appropriate for regulating foods that are for special dietary use. Such foods are those specifically represented or purported to be useful as part of a weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although such products can be useful in reducing or maintaining body weight). The agency proposed to retain those provisions in § 105.66.

Numerous comments that responded to the nutrient content claims proposal supported the continued allowance of the statement ''Useful Only in Not Promoting Tooth Decay'' in proposed § 101.13(o)(8) on the label of chewing gums that claim to be ''sugar free.'' However, at least one comment suggested that only the statements ''not a reduced calorie food'' and ''not a low (free) calorie food'' were appropriate. The comment specifically suggested that FDA should disallow the statement ''useful only in the prevention of tooth decay'' with ''sugar free'' claims. The comment also implied that FDA should disallow the statement ''not for weight control'' with ''sugar free'' (58 FR 2302 at 2325, January 6, 1993).

Based upon its review of the comments, FDA determined that there was no compelling reason to disallow the statement ''not for weight control.'' However, the agency concluded that the statement ''Useful Only in Not Promoting Tooth Decay'' should not be allowed because it is an unauthorized health claim; that is, it is a statement that characterizes the relationship of a nutrient (i.e., the sugar alcohol used in the product) to a disease (i.e., dental caries). Further, the agency deleted, as unnecessary, the exemption in proposed § 101.13(o)(8) that would have allowed a ''sugar free'' claim on chewing gums containing sugar alcohols and the statement about not promoting tooth decay, because the agency had decided not to define sugar alcohols as ''sugars.'' Therefore, FDA deleted the proposed paragraph (o)(8) from the final rule adopting § 101.13. The final rules effecting this change, entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' (58 FR 2302) (hereinafter referred to as the nutrient content claims final rule) and ''Food Labeling: Label Statements on Foods For Special Dietary Use'' (58 FR 2427) (hereinafter referred to as the special dietary use final rule), published in the **Federal Register** of January 6, 1993.

II. Amendment to Section 105.66

A. *Objections and Requests for a Hearing*

Following publication of the special dietary use final rule, a manufacturer, a trade association, and a ''working group'' of manufacturers filed timely objections to the rule revising § 105.66(f)

by removing the statement ''Useful Only in Not Promoting Tooth Decay'' from those statements that can be used in conjunction with a ''sugar free'' claim. They requested a formal evidentiary hearing on their objections. Two other manufacturers submitted general comments, and a professional association resubmitted, as comments to the special dietary use final rule, comments that it had filed regarding the November 27, 1991, proposed rules on food labeling.

The provision of § 105.66(f) that was the subject of the objections was adopted under section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)). Section 701(e)(1) of the act provides that any person adversely affected by a regulation issued under that section may file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating reasonable grounds therefor'' and may request a public hearing based upon such objections. Under section 701(e) of the act, objections and a request for a hearing on a particular regulation act to automatically stay or delay the effective date of the action to which objections are raised (section 701(e)(2) of the act). Thus, the revision to § 105.66(f) that would remove the statement ''Useful Only in Not Promoting Tooth Decay'' from those statements that can be used in conjunction with a ''sugar free'' claim was automatically stayed as of February 5, 1993.

B. *Standards for Granting a Hearing*

FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing. Specific criteria for determining whether a hearing has been justified are set forth in 21 CFR 12.24(b). A hearing will be granted if the material submitted shows that: (1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issues were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal; and (5) the action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' *Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980) reh. den., 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Wescott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test. *Georgia Pacific Corp.* v. *U.S. E.P.A.,* 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law. (See Rule 56, Federal Rules of Civil Procedure.) The same principle applies in administrative proceedings.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. *Pineapple Growers Association* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281 (8th Cir. 1959), cert. denied, 362 U.S. 911 (1960). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States* v. *Consolidated Mines & Smelting Co.,* 455 F.2d 432 (9th Cir. 1971).) In other words, a hearing is justified only if the objections are made in good faith, and if they ''draw in question in a material way the underpinnings of the regulation at issue.'' *Pactra Industries* v. *CPSC,* 555 F.2d 677 (9th Cir. 1977) (see also *Community Nutrition Institute* v. *Young,* 773 F.2d 1356 (D.C. Cir. 1985)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc.* v. *FPC,* 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir.), cert. denied, 358 U.S. 872 (1958).)

In summary, a hearing request should present sufficient credible evidence to raise a material issue of fact, and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

C. *Analysis of Objections and Request for a Hearing and Related Comments*

1. The three objectors and one of the comments stated that the agency had not provided adequate notice or opportunity for comment on its decision to remove the provision providing for the use of the statement ''Useful Only in Not Promoting Tooth Decay.'' The objectors presented a number of arguments as support. First, two of the objectors stated that all of the previous proposals related to the final rule implied that the agency was going to retain the phrase ''Useful Only in Not Promoting Tooth Decay.'' Secondly, one objector stated that the meaning of the agency's statement in the nutrient content claims proposal that it planned at some point to reevaluate its earlier determination regarding sugar-free products was at least ambiguous. The other two objectors stated that this statement only served to alert interested persons that FDA may decide in the future to propose revisions to the rule allowing use of the statement ''Useful Only in Not Promoting Tooth Decay'' but that such revisions could have gone in either direction. These objectors concluded that the decisions to delete § 105.66(f) and to subject the phrase ''Useful Only in Not Promoting Tooth Decay'' to the requirements of health claims were in no sense logical outgrowths of FDA's November 1991 proposal.

In considering the objection that the agency did not provide adequate notice and opportunity for comment in its actions revoking the provision for the phrase ''Useful Only in Not Promoting Tooth Decay,'' it is important to understand exactly what FDA did in the nutrient content claims proposal. FDA was not merely proposing to carry forward the provisions of the ''sugar free'' claim unchanged from the existing regulations. Rather, FDA was proposing to find that a fundamental change in the character of this claim had been worked

by the 1990 amendments; i.e., it had changed from a special dietary use claim that was directed at a limited segment of the population to a nutrient content claim directed to the general population. Thus, FDA was not merely proposing to change the location of the provisions on this claim. It was asking whether the ''sugar free'' claim is an appropriate nutrient content claim, and whether it is appropriate to retain the qualifiers that had been used to clarify this claim.

The question that the objectors' arguments raise is whether the agency's decision that the ''Useful Only in Not Promoting Tooth Decay'' statement is a health claim, under the requirements of the 1990 amendments, and that it cannot be used as a qualifier of the nutrient content claim, is the logical outgrowth of the proposal. In *Chocolate Manufacturers Association* v. *Block*, 755 F.2d 1098, 1105 (4th Cir. 1985), the Fourth Circuit said that the question that the logical outgrowth test raises is whether the final rule materially altered the issues involved in the rulemaking; that is, whether the final rule substantially departed from the terms or substance of the proposed rule.

In its final decision on the ''Useful Only in Not Promoting Tooth Decay'' statement, FDA was acting well within the scope of the proposed rule. The issue in the proposal was whether ''sugar free'' and its qualifiers constituted an appropriate nutrient content claim, and that is the issue that the agency decided in the final rule.

The key point in considering the adequacy of the notice that FDA provided is the fact that FDA never specifically raised the question of whether the ''Useful Only in Not Promoting Tooth Decay'' qualifier could be considered to be a health claim. The question that, thus, must be considered is whether this omission was sufficiently significant as to provide a basis for concluding that the agency did not give proper notice.

This question is answered by *International Harvester Co.* v. *Ruckelshaus*, 478 F.2d, 615, 632 n.51 (D.C. Cir. 1973). In Footnote 51, the court stated:

> As we have stated in an analogous context of rule-making proceedings before the Federal Communications Commission, where petitioners have argued that the Commission was ''changing the rules in the middle of the game'' when it took into consideration factors not specifically indicated in its Section 4(a) notice under the Administrative Procedure Act, 5 U.S.C. § 1001(a), ''[s]urely every time the Commission decided to take account of some additional factor it was not required to start the proceedings all over again. If such were the rule the proceedings might never be terminated.'' *Owensboro On the Air* v. *United States*, 104 U.S. App. D.C. 391, 397, 262 F.2d, 702, 708 (1958); *Logansport Broadcasting Corp.* v. *United States*, 93 U.S. App. D.C. 342, 346, 210 F.2d, 24, 28 (1954).

Thus, the agency need not have mentioned the specific factor on which it ultimately relied in the proposal as long as the basic issue remained the same, which it did.

In the nutrient content claims proposal, FDA was raising the question of whether particular statements are appropriate to be made as nutrient content claims for food products. With respect to one such statement, ''Useful Only in Not Promoting Tooth Decay,'' several comments were received in support of, and one comment in opposition to, retention of this statement as part of the ''sugar-free'' claim. FDA's decision was that this statement was not a nutrient content claim. Thus, the objectors' arguments that an adequate notice and opportunity for comment were not provided, and that the final rule was not the logical outgrowth of the proposal, are without merit.

2. In arguing that the agency had not provided adequate notice and an opportunity for comment, one objector referred to a statement by the agency concerning the persuasiveness of data in supporting the noncariogenicity of sugar alcohols (polyols) that appeared in the final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (hereinafter referred to as the ''mandatory nutrition labeling final rule'') (58 FR 2079 at 2099). The firm also pointed to other statements made by FDA in reference to health claims and its intentions regarding sugar alcohols that the objector claimed evidenced that FDA's action was motivated by doubts about the validity of the ''Useful Only in Not Promoting Tooth Decay'' claim.

Nowhere did FDA say, as the objector implies, that it became aware of new data casting doubt about the noncariogenic properties of sugar alcohols. What the agency did say was that it wanted to ensure that the statement continued to be valid. It is clear, however, that the agency's final action on the ''Useful Only in Not Promoting Tooth Decay'' statement was not motivated by any concern about the continuing validity of the claim. It was based solely on the legal conclusion about the status of the claim that the agency reached after reconsidering whether to continue to provide for use of the statement in light of the comments that were submitted (see 58 FR 2302 at 2326). Thus, the objector's argument that there was no suggestion that FDA had become aware of new information casting doubt on the noncariogenic attributes of sugarless products is simply beside the point.

3. The objectors argued that the statement ''Useful Only in Not Promoting Tooth Decay'' has a long history of use, and that its history of use was as a disclaimer and not as a claim. The objectors argued that, as a disclaimer, the phrase is an integral part of the nutrient content claim ''sugar free'' and, thus, under the provisions of the last sentence of section 403(r)(1) of the act (21 U.S.C. 343(r)(1)), i.e., ''a claim subject to clause (A) is not subject to clause (B),'' cannot be treated as a health claim.

Before the passage of the 1990 amendments, how the statement ''Useful Only in Not Promoting Tooth Decay'' had been used may have had some significance in determining whether to permit its continued use. However, the agency had to review the use of the statement in view of the changed circumstances effected by the new law. Under section 403(r)(1)(B) of the act, a claim that characterizes the relationship of any nutrient which is of the type required in section 403(q)(1) or (q)(2) of the act to be in the label or labeling of a food to a disease or a health-related condition is a health claim. The statement on tooth decay meets both elements of this definition. Sugar alcohols are a category of nutrients for nutrition labeling purposes (see 21 CFR 101.9(c)(6)(iii)), and tooth decay is a disease. Thus, no matter how this claim has been used, the agency must pay attention to the law as it is now written, and the law says that if such a statement appears on the food label, it will misbrand the food unless authorized by FDA under section 403(r)(3) of the act. The agency was merely recognizing what the law requires on its face in saying in the nutrient content claims final rule that the phrase ''Useful Only in Not Promoting Tooth Decay'' is a health claim. It does not meet the definition of nutrient content claim because it does not provide any information that constitutes a nutrient content claim; i.e., that characterizes the level of any nutrient.

4. The objectors also argued that the phrase ''Useful Only in Not Promoting Tooth Decay'' is an integral, indispensable part of the nutrient content claim that provides important information to help the consumer understand the intent of the ''sugar free'' claim. In making this argument, the objectors relied on the history of the

''sugar free'' claim as a special dietary use claim, and the fact that section 403(j) of the act on foods for special dietary use says such food is misbranded ''unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulation prescribes as, necessary in order fully to inform purchasers of its value for such uses.''

Assuming that section 403(j) of the act is relevant to how a nutrient content claim is defined, what the objectors do not recognize or deal with is the fact that section 403(j) of the act is a grant of discretion to the Secretary (''as the Secretary determines'') with regard to what information is necessary to inform consumers of the value of a food for special dietary use. FDA must exercise its discretion in accordance with the law, however. Section 403(r)(1)(B) of the act on its face makes the statement ''Useful Only in Not Promoting Tooth Decay'' a health claim and not a nutrient content claim or an indispensable part of a nutrient content claim. Thus, the act, as revised by the 1990 amendments, precludes the agency from treating this statement in any other way than as a health claim. Thus, the agency's discretion under section 403(j) of the act (and, given the agency's decision to treat ''sugar free'' as a nutrient content claim, under section 403(r)(1)(A) of the act) is limited by section 403(r)(1)(B) of the act. ''Useful Only in Not Promoting Tooth Decay'' simply is not available for use as part of a nutrient content claim.

5. The objectors argued that, because ''Useful Only in Not Promoting Tooth Decay'' had not been viewed as a drug claim, it is not a health claim. The objectors stated that there has never been any indication during the use of the statement that it constituted a drug claim.

FDA believes that this argument misinterprets the intent of the 1990 amendments and is without merit. The fact that, under section 201(g)(1) of the act (21 U.S.C. 321(g)(1)), a claim that is authorized under section 403(r)(3) or 403(r)(5)(D) of the act would not subject a food to regulation as a drug has apparently somehow created the incorrect impression that the process for authorizing a health claim for a food is an alternative to obtaining approval for a drug claim. There is nothing in either section 201(g)(1) or section 403(r) of the act that either states or implies that health claims are claims that would be drug claims if not authorized by the agency. The fact that an authorized health claim will not make a food product a drug does not mean that an unauthorized health claim will.

In contrast to a drug claim, a health claim provides information about how diet can help reduce a person's risk of developing certain diet-related diseases. The ''Useful Only in Not Promoting Tooth Decay'' statement does exactly what a health claim is supposed to do. It tells the consumer that including foods sweetened with sugar alcohols in his or her diet will affect his or her risk of developing dental cavities. (The question of the scientific validity of this claim is addressed in a proposal published elsewhere in this issue of the **Federal Register**.) Thus, there is nothing in the act that would preclude regulating ''Useful Only in Not Promoting Tooth Decay'' as a health claim. Quite the contrary, the act compels that this claim be regulated as such a claim.

6. A comment from a manufacturer noted that the date for submission of objections to the final rule provided that objections must be submitted by December 10, 1992, rather than being 30 days after the date of publication in the **Federal Register** (i.e., February 4, 1993). The letter contained no specific objections concerning the content of the final rule.

The error identified in the comment occurred in the ''Objections'' section of the special dietary use final rule (58 FR 2427 at 2430). The caption **DATES** at the beginning of the document listed the correct date of February 5, 1993, for the submission of objections and requests for hearing. Additionally, FDA published a document in the **Federal Register** of April 1, 1993 (58 FR 17104), correcting the reference to December 10, 1993. FDA is not aware of any difficulty presented to objectors by the presence of the incorrect date in the special dietary use final rule. Therefore, it finds nothing in their comment that would warrant further action by the agency.

D. *Conclusions on Objections and Request for a Hearing*

Under part 12 (21 CFR part 12), a request for a hearing shall be granted if there is a genuine and substantial issue of fact. The arguments presented by the various objectors did not present any genuine and substantial issues of fact. Accordingly, having fully considered the issues raised by the objectors in regards to the special dietary use final rule, FDA finds that they have no merit and is hereby denying the requests for a hearing.

III. Amendment to Section 101.60

A. *Request for a Stay of Effectiveness*

A trade association and a ''working group'' of manufacturers independently submitted the same joint petition requesting that the agency stay the effectiveness of the issuance of § 101.60(c) while the specific issues raised in their joint petition are being reconsidered. They also asked for a stay of any administrative action by FDA under its determination that ''Useful Only in Not Promoting Tooth Decay'' is an unauthorized health claim. Finally, they asked that FDA issue an affirmative statement on enforcement policy with respect to the disclaimer during the period of May 8, 1993, to May 8, 1994.

FDA provides in part 10 (21 CFR part 10) of its regulations that an interested person may request that the agency stay the effective date of any administrative action (§ 10.35).

The agency is responding to the various requests for reconsideration in this document. Because FDA has determined that a hearing need not be held on the amendments to § 105.66 and that there is no basis for reconsideration of the decision and regulations in question, the question of a stay pending reconsideration is moot. However, FDA notes that the new provisions of § 105.66(f) were stayed automatically by the operation of section 701(e) of the act upon the filing of objections to the special dietary use final rule. Additionally, the agency notes that it has refrained administratively from taking any action pending its resolution of the objections and requests for a hearing. Also, under its enforcement discretion, the agency plans no regulatory action on the use of the phrase ''Useful Only in Not Promoting Tooth Decay'' pending its final action on the proposal published elsewhere in this issue of the **Federal Register** in response to the health claim petition that has been submitted for sugar alcohols.

B. *Request for Reconsideration*

A trade association of manufacturers and a ''working group'' of manufacturers independently filed a joint petition for reconsideration of the agency's decision ''concerning the use of the 'useful only in not promoting tooth decay' disclaimer for 'sugar free' foods.'' The petitioners requested reconsideration of the agency's decisions to: (1) Remove existing § 105.66(f) from the republished rules governing the labeling of foods for special dietary uses; (2) add new § 101.60(c) without including ''Useful Only in Not Promoting Tooth Decay'' as a permitted disclaimer, where appropriate for caloric sugar free products; and (3) take the position in the preamble to the nutrient content claims regulation that this disclaimer represents an unauthorized health

claim. The petitioners made the same arguments in support of their request for reconsideration that they made in support of their objections to the agency's actions and determinations concerning the phrase ''Useful Only in Not Promoting Tooth Decay'' (see discussion in section II of this document).

Under § 10.33(b), an interested person may request reconsideration of all or part of a decision of the agency. The agency may grant a petition for reconsideration when it determines that reconsideration is in the public interest and in the interest of justice. The agency shall grant a petition for reconsideration in any proceeding if it determines that all of the following apply: (1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered; (2) the petitioner's position is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting reconsideration; and (4) reconsideration is not outweighed by public health or other public interests.

The agency has discussed in section II of this document its findings with respect to each of the arguments presented in the petitions for reconsideration. The arguments presented by the petitions do not identify any information that was not properly considered or that raises a genuine issue of fact. Accordingly, finding that they are without merit, FDA is denying the petitions for reconsideration of its decision concerning the statement ''Useful Only in Not Promoting Tooth Decay.'' Further, the agency notes that the petition for reconsideration is now moot based upon the submission by the petitioners of a health claim petition concerning the noncariogenicity of sugarless food products sweetened with sugar alcohols, and the agency's tentative decision discussed elsewhere in this issue of the **Federal Register**, to grant that petition.

Dated: July 7, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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